

### **REMARKS**

The above-identified application has been considered in view of the Final Office Action that was mailed on July 24, 2009. Claims 1-35 are currently pending. In view of the following remarks and arguments, Applicant respectfully submits that each of pending claims 1-35 is allowable over the references of record, and accordingly, respectfully requests reconsideration and allowance of these claims.

As an initial matter, Applicant would like to thank Examiner Smith for taking the time to discuss the above-identified application with Applicant's representative, Michael J. Debono, during a telephonic interview that was held on September 15, 2009.

In the Final Office Action, claims 1-5, 7-9, 12-16 and 18-35 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,215,521 to Cochran, *et al.* (hereinafter "Cochran") in view of U.S. Patent No. 5,149,159 to Bardes, *et al.* (hereinafter "Bardes"). Applicant respectfully submits, however, that the combination of Cochran and Bardes fails to render the subject matter of claims 1-5, 7-9, 12-16, and 18-35 obvious.

Pursuant to 35 U.S.C. §103(a), "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art," then the subject matter is not patentable. (Emphasis added).

Independent claim 1 recites “[a] tissue removal device” that includes, *inter alia*, a bag “having folds including at least one transverse fold” that is repositionable between unfolded position and folded conditions, “whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.”

Independent claim 19 recites “[a] method of collapsing a bag of a tissue removal device” that includes the steps of, *inter alia*, providing a tissue removal device with a bag that is repositionable between unfolded and folded positions, and:

folding the bag transversely with respect to the longitudinal axis such that a first transverse fold is formed . . . whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Independent claim 28 recites “[a] minimally invasive tissue removal device” that includes, *inter alia*, a bag that is repositionable between unfolded and folded positions, wherein the bag is:

folded over onto itself so as to form at least one transverse fold . . . such that an axial length of the bag assembly is increased and a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, that is relatively smaller as compared to a distal portion of the tissue removal device including a like bag, in a folded position, that is devoid of said at least one transverse fold.

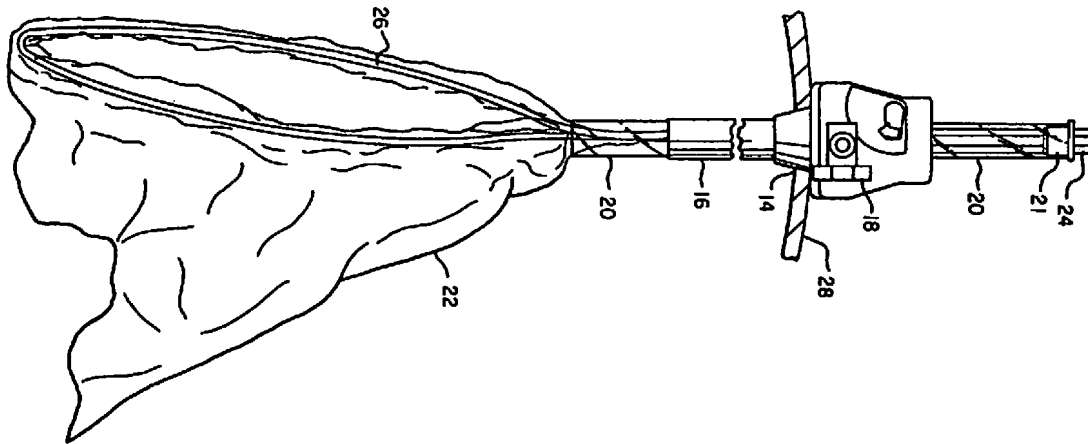
Independent claim 31 recites “[a] minimally invasive tissue removal device” that includes, *inter alia*, a bag that is repositionable between unfolded and folded positions, wherein:

the bag is folded over onto itself so as to form at least one fold extending along an axis that is substantially non-parallel and non-orthogonal to the longitudinal axis of the shaft, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Independent claim 33 recites “[a] method of collapsing a bag of a tissue removal device” that includes the steps of, *inter alia*, “providing a minimally invasive tissue removal device” including a bag that is repositionable between unfolded and folded positions, and:

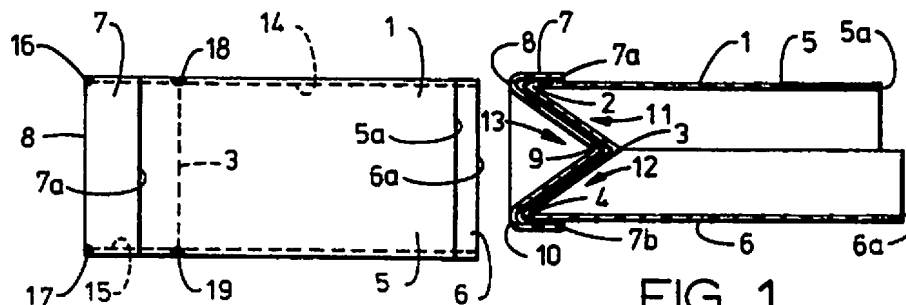
folding the bag such that at least one transverse fold is formed, the at least one transverse fold extending transversely with respect to the longitudinal axis, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position, less than a transverse cross-sectional dimension otherwise defined by the distal portion of the tissue removal device including a like bag, in a folded position, devoid of said at least one transverse fold.

Cochran relates to an organ retrieval apparatus including an entrapment envelope 22 that is inserted into an inflated body cavity through an elongate sheath 20. (*See* col. 8, lines 12-18; FIG. 4 reproduced below).



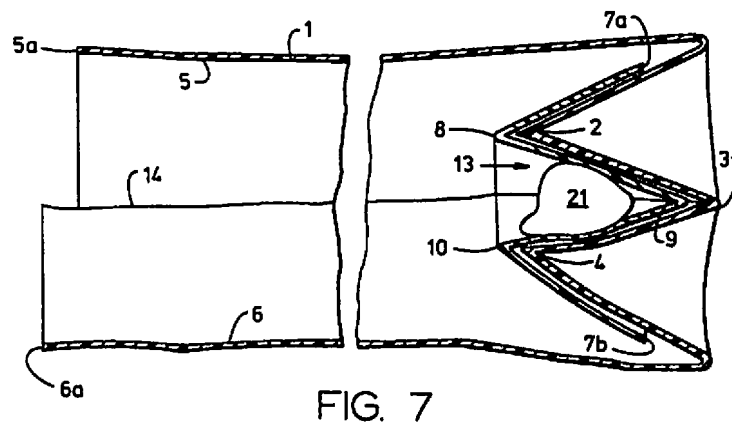
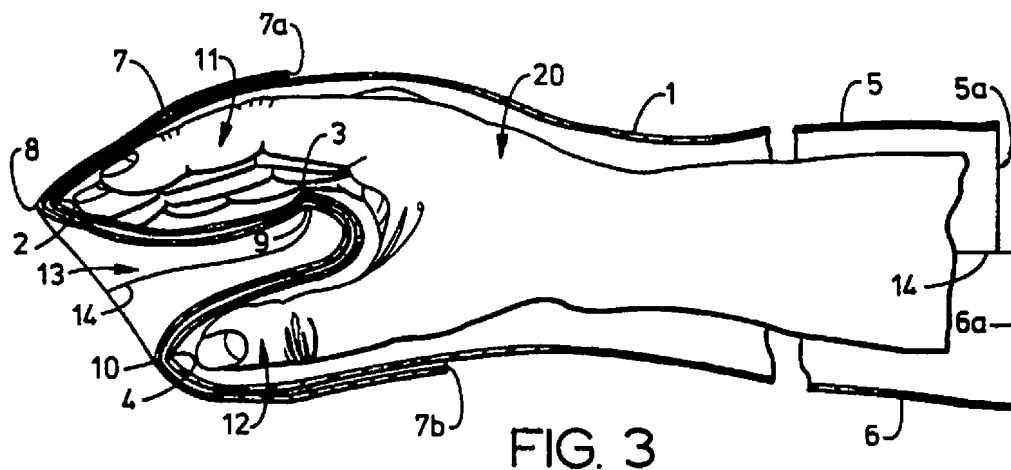
**FIG. 4**

Bardes relates to “a disposable collector and container in the form of a glove-like bag.” (Col. 1, lines 8-9). Specifically, Bardes discloses a collector including a strip 1 that is connected to a second ply 7. (See col. 3, lines 49-64; FIGS. 1, 2 below). The strip 1 is folded along transverse fold lines 2, 3, 4 to form a closed end with a gusset having a “W” shape. (See col. 3, lines 54-56; FIGS. 1, 7 below). The closed, gusseted end of the collector forms three pockets, i.e., two interior pockets 11, 12 and one exterior pocket 13. (See col. 4, lines 4-7; FIGS. 1, 3, 7 below).



**FIG. 2**

**FIG. 1**



In the Final Office Action, the entrapment envelope 22 described in Cochran was characterized as the “bag” recited in claims 1-5, 7-9, 12-16, and 18-35. While the Examiner argued that the Cochran envelope 22 is capable of folding transversely, the Examiner acknowledged that the envelope 22 fails to include the at least one transverse fold also included as part of the claimed subject matter, but relied upon Bardes for disclosure of this concept. (*See* Final Office Action, page 3).

Regarding Bardes, with reference to FIG. 7 (reproduced above), the Examiner stated that:

Bardes et al. disclose [*sic*] a sample retrieval instrument having a bag with at least one transverse fold at its distal end. The transverse fold is located such that the cross sectional area of the distal end of the apparatus is reduced when the fold is present forming a pouch area which allows a specimen to be collected. The pouch includes a first and second edge with bag folds including at least one transverse fold extending from the first edge toward the second edge such that an angle less than 90 degrees is defined relative to the longitudinal axis (Figure 7). Devoid the fold, the area would have a larger cross section. (Final Office Action, pages 3-4).

Applicant respectfully disagrees with the Examiner's characterization of Bardes.

As discussed in the Amendment that was filed on April 1, 2009, according to the present disclosure, the bag 40 recited in the pending claims is repositionable between unfolded and folded positions, e.g., in preparation for packaging, as seen below in the transition between FIGS. 3 and 4. (*See* page 13, lines 15-18). Specifically, the present disclosure states that repositioning the bag 40 along a transverse fold 47 "has been found to produce a low profile folded bag, such that smaller diameter tubes can be used." (Page 13, lines 18-20). In other words, including the transverse fold 47 in the bag 40 allows for a reduction in the transverse profile and dimensions of the bag 40 when the bag 40 is in a folded condition on or around bag support 20.

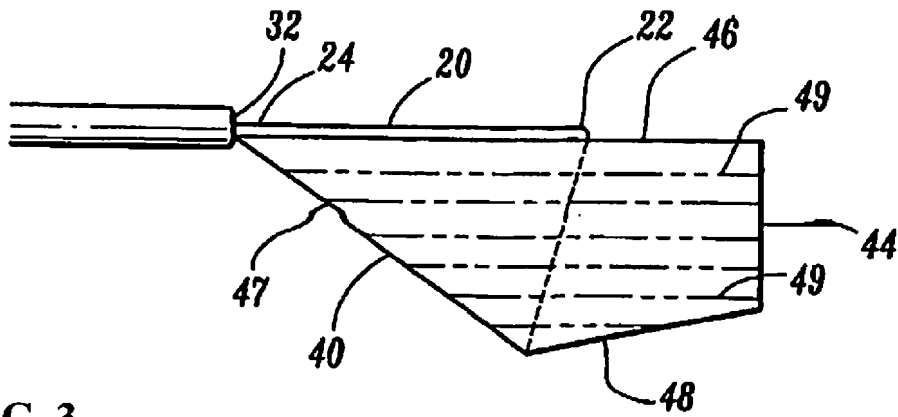


FIG. 3

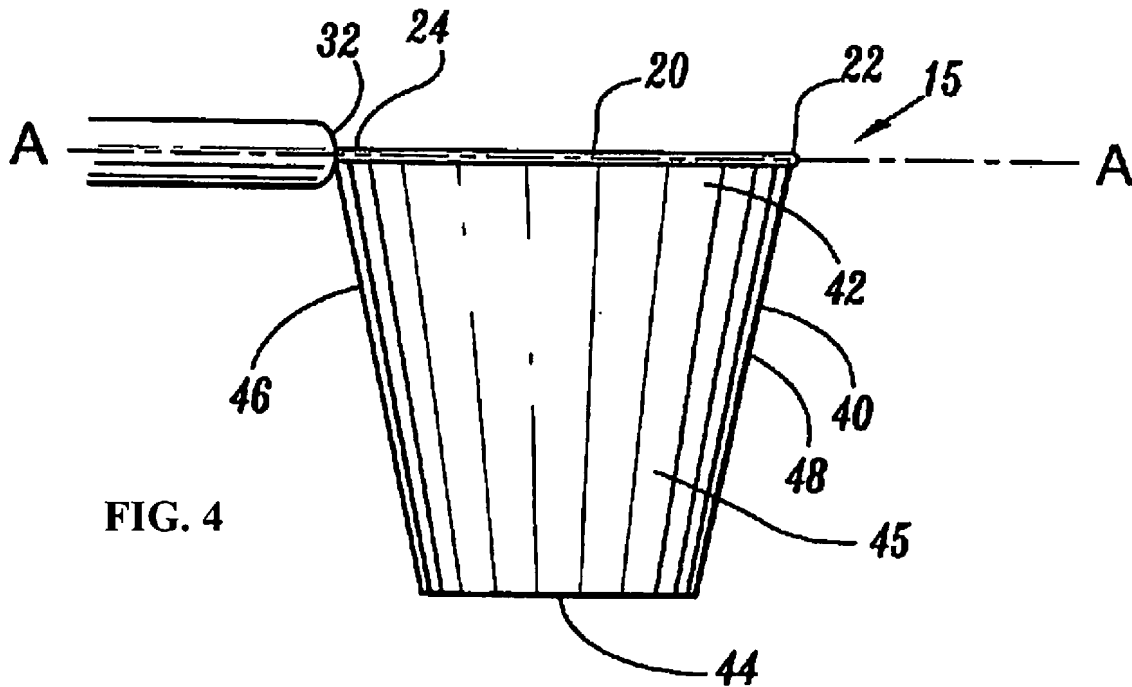
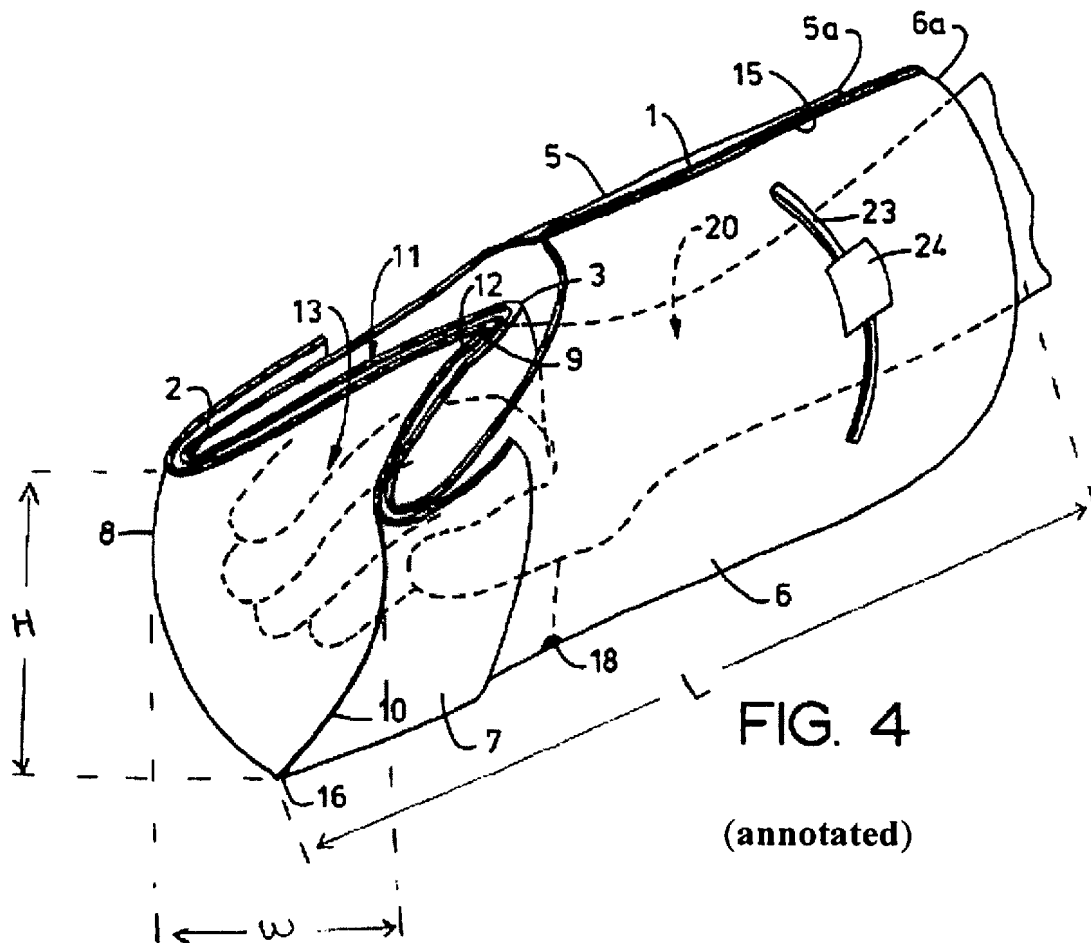


FIG. 4

In contrast, Bardes indicates that the folds 2, 3, 4 form the aforementioned gusset and the pockets 11, 12, 13 in the collector.

With reference to the annotated version of FIG. 4 reproduced below, Applicant respectfully submits that while the folds 2, 3, 4 allow the overall length "L" of the collector to be reduced by folding the strip 1 inwardly and proximally, the folds 2, 3, 4 do nothing to reduce either the width "W" or height "H" of the collector. Thus, Applicant respectfully submits that the folds 2, 3, 4 fail to reduce any dimension of the Bardes collector that may be properly characterized as "transverse."





To the contrary, Applicant respectfully submits that by folding the strip 1 along the fold lines 2, 3, 4, material is drawn inwardly and proximally into the interior portion of the strip 1 to thereby define the gusseted “W” shape seen in FIG. 4 above. This additional material actually increases the width “W” of the collector, and not only creates the exterior 13, which houses the specimen to be collected, but allows for manipulation of the clinician’s fingers to facilitate grasping of the specimen. Were the folds 2, 3, 4 to reduce one or more transverse dimensions of the collector, as alleged in the Final Office Action, the clinician’s ability to open and close her hand would be substantially limited, if not entirely eliminated, thus frustrating the very purpose of the disclosed collector.

Applicant notes the disclosure in Bardes indicating that after a specimen has been collected, the open proximal end of the collector is pulled distally, i.e., towards the clinician’s fingers, to turn the collector inside out. (See col. 5, lines 59-68). However, in this position, as above in FIG. 7, the end of the collector including the gusseted “W” shaped portion tapers outwardly relative to the longitudinal axis, thereby increasing the transverse dimension of the collector.

Accordingly, Applicant respectfully submits that Bardes fails to disclose, or even suggest, a bag “having folds including at least one transverse fold” that is repositionable between unfolded position and folded conditions, “whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position,” as recited in independent claim 1, (emphasis added), or “[a] method of collapsing a bag of a

tissue removal device” that includes the steps of, *inter alia*, providing a tissue removal device with a bag that is repositionable between unfolded and folded positions, and folding the bag such that at least one transverse fold is formed, “whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position,” as recited in independent claim 19. (Emphasis added).

Additionally, Applicant respectfully submits that Bardes fails to disclose, or even suggest, a bag that is repositionable between unfolded and folded positions, wherein the bag is “folded over onto itself so as to form at least one transverse fold . . . such that an axial length of the bag assembly is increased and a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension,” as recited in independent claim 28, (emphasis added), or “a bag that is repositionable between unfolded and folded positions, wherein the bag is folded over onto itself so as to form at least one fold extending along an axis that is substantially non-parallel and non-orthogonal to the longitudinal axis of the shaft, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position,” as recited in independent claim 31. (Emphasis added).

Likewise, Applicant respectfully submits that Bardes also fails to disclose, or even suggest, “a method of collapsing a bag of a tissue removal device” that includes the steps of, *inter alia*, “providing a minimally invasive tissue removal device” including a bag that is repositionable between unfolded and folded positions” and “folding the bag such that at least one transverse fold is formed, the at least one transverse fold extending transversely with respect to

the longitudinal axis, whereby a distal portion of the tissue removal device defines a reduced transverse cross-sectional dimension, when the bag is in the folded position,” as recited in independent claim 33. (Emphasis added).

In view of the foregoing discussion concerning the Bardes collector, Applicant respectfully submits that Bardes fails to remedy the deficiencies in Cochran acknowledged in the Final Office Action. Accordingly, and for at least this reason, *inter alia*, Applicant respectfully submits that neither Cochran, nor Bardes, nor any proper combination thereof, discloses or suggests the subject matter of independent claims 1, 19, 28, 31, and 33 as a whole, and therefore, that the combination of Cochran and Bardes fails to render the subject matter of independent claims 1, 19, 28, 31, and 33 obvious. As such, Applicant respectfully submits that independent claims 1, 19, 28, 31, and 33 are allowable over Cochran in view of Bardes under 35 U.S.C. §103(a).

Since claims 2-5, 7-9, 12-16, 18, 20-27, 29, 30, 32, 34, and 35 depend either directly or indirectly from independent claims 1, 19, 28, 31, and 33, and include each element recited therein, for at least the reasons that independent claims 1, 19, 28, 31, and 33 are allowable over Cochran in view of Bardes under 35 U.S.C. §103(a), *inter alia*, Applicant respectfully submits that the subject matter of claims 2-5, 7-9, 12-16, 18, 20-27, 29, 30, 32, 34, and 35 as a whole is also allowable over Cochran in view of Bardes under 35 U.S.C. §103(a).

Claims 1, 4, and 6 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Bardes and further in view of U.S. Patent No. 5,899,694 to Summer (hereinafter "Summer"). Applicant respectfully submits, however, that the combination of Cochran, Bardes, and Summer fails to render the subject matter of claims 1, 4, and 6 obvious.

In the Final Office Action, the Examiner acknowledged that the combination of Cochran and Bardes fails to disclose a sheath that is fabricated from a flexible heat-shrinking polymer, as recited in claims 4 and 6, but relied on Summer for disclosure of this concept.<sup>1</sup>

As discussed above, the combination of Cochran and Bardes fails to suggest the subject matter of independent claim 1 as a whole. Assuming, *arguendo*, that the Examiner's purported characterization of Summer is accurate, including the sheath purportedly disclosed therein would fail to cure the aforescribed deficiencies in the combination of Cochran and Bardes.

Accordingly, and for at least this reason, *inter alia*, Applicant respectfully submits that the combination of Cochran, Bardes, and Summer fails to suggest the subject matter of independent claim 1 as a whole, and therefore, that the combination of Cochran, Bardes, and Summer fails to render the subject matter of independent claim 1 obvious. Accordingly, Applicant respectfully submits that independent claim 1 is allowable over Cochran in view of Bardes and Summer under 35 U.S.C. §103(a). Since claims 4 and 6 depend directly and

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<sup>1</sup> Applicant believes that the Examiner inadvertently, but mistakenly, included claim 1 in the rejection under 35 U.S.C. §103(a) over Cochran in view of Bardes and Summer, in that independent claim 1 does not recite the sheath purportedly disclosed in Summer. However, in the interests of responding fully to the rejection, Applicant will overlook the inclusion of claim 1, and the rejection will be addressed with respect to claims 1, 4, and 6.

indirectly from independent claim 1, respectively, and include each element recited therein, for at least the reasons that independent claim 1 is allowable over Cochran in view of Bardes and Summer under 35 U.S.C. §103(a), *inter alia*, Applicant respectfully submits that the subject matter of claims 4 and 6 as a whole is also allowable over Cochran in view of Bardes and Summer under 35 U.S.C. §103(a).

Claims 10 and 11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Bardes and further in view of U.S. Patent No. 6,402,722 to Snow *et al.* (hereinafter "Snow"). Applicant respectfully submits, however, that the combination of Cochran, Bardes, and Snow fails to render the subject matter of claims 10 and 11 obvious.

In the Final Office Action, the Examiner acknowledged that the combination of Cochran and Bardes fails to disclose "a cord operatively connected to the tear line for facilitating the tearing of the sheath along the tear line," as recited in claim 10, but relied on Snow for disclosure of this concept.

As previously discussed, the combination of Cochran and Bardes fails to suggest the subject matter of independent claim 1 as a whole. Assuming, *arguendo*, that the Examiner's purported characterization of Snow is accurate, including the cord purportedly disclosed therein would fail to cure the aforescribed deficiencies in the combination of Cochran and Bardes.

Accordingly, and for at least this reason, *inter alia*, Applicant respectfully submits the combination of Cochran, Bardes, and Snow fails to suggest the subject matter of independent

claim 1 as a whole, and therefore, that the combination of Cochran, Bardes, and Snow fails to render the subject matter of independent claim 1 obvious. As such, Applicant respectfully submits that independent claim 1 is allowable over Cochran in view of Bardes and Snow under 35 U.S.C. §103(a). Since claims 10 and 11 depend either directly or indirectly from independent claim 1, and include each element recited therein, for at least the reasons that independent claim 1 is allowable over Cochran in view of Bardes and Snow under 35 U.S.C. §103(a), *inter alia*, Applicant respectfully submits that claims 10 and 11 are also allowable over Cochran in view of Bardes and Snow under 35 U.S.C. §103(a).

Claim 17 was rejected under 35 U.S.C. §103(a) as being unpatentable over Cochran in view of Bardes and further in view of U.S. Patent No. 5,480,404 to Kammerer, *et al.* (hereinafter "Kammerer"). Applicant respectfully submits, however, that the combination of Cochran, Bardes, and Kammerer fails to render the subject matter of claim 17 obvious.

In the Final Office Action, the Examiner acknowledged that the combination of Cochran and Bardes fails to disclose a bag having a trapezoidal shape, as substantially recited in claim 17, but relied on Kammerer for disclosure of this concept.

As previously discussed, the combination of Cochran and Bardes fails to suggest the subject matter of independent claim 1 as a whole. Assuming, *arguendo*, that the Examiner's purported characterization of Kammerer is accurate, including the trapezoidal bag purportedly disclosed therein would fail to cure the aforescribed deficiencies in the combination of

Cochran and Bardes.

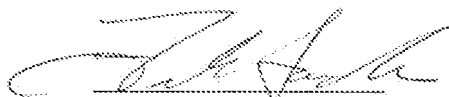
Accordingly, and for at least this reason, *inter alia*, Applicant respectfully submits that the combination of Cochran, Bardes, and Kammerer fails to suggest the subject matter of independent claim 1 as a whole, and therefore, that the combination of Cochran, Bardes, and Kammerer fails to render the subject matter of independent claim 1 obvious. As such, Applicant respectfully submits that independent claim 1 is allowable over Cochran in view of Bardes and Kammerer under 35 U.S.C. §103(a). Since claim 17 depends directly from independent claim 1, and includes each element recited therein, for at least the reasons that independent claim 1 is allowable over Cochran in view of Bardes and Kammerer under 35 U.S.C. §103(a), *inter alia*, Applicant respectfully submits that the subject matter of claim 17 as a whole is also allowable over Cochran in view of Bardes and Kammerer under 35 U.S.C. §103(a).

In view of the foregoing remarks and arguments, Applicant respectfully submits that claims 1-35 are allowable over the references of record, and accordingly, respectfully requests reconsideration and allowance of these claims.

Should the Examiner have any questions concerning the present Amendment, or feel that an interview would be helpful in resolving any outstanding matters, the Examiner is sincerely invited to contact Applicant's undersigned attorney whenever convenient.

An early and favorable response on the merits is earnestly requested.

Respectfully submitted,



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